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FULBRIGHT & JAWORSKI
MARKET SQUARE
801 PENNSLYVANIA, N.W.
WASHINGTON, DC 200042604

EXAMINER	
FALK, ANNE MARIE	
ART UNIT	**PAPER NUMBER**
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/615,518	LEIDEN, JEFFREY M.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 24-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 24-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/8/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed May 8, 2007 (hereinafter referred to as "the response") has been entered. Claims 1 and 24 have been amended, Claims 12-23 have been cancelled, and Claim 37 has been newly added.

Applicants elected the species "growth factor" in the response filed April 3, 2006.

Claims 1-11 and 24-37 remain pending in the instant application.

The rejection of Claims 1-23 for obviousness-type double patenting is withdrawn in view of the terminal disclaimer filed May 8, 2007 and the cancellation of Claims 12-23.

The rejection of Claims 24-36 for obviousness-type double patenting is withdrawn in view of the terminal disclaimer filed May 8, 2007.

The objection to Claims 12-23 under 37 CFR 1.75 as being a substantial duplicate of Claims 1-11 is withdrawn in view of the cancellation of Claims 12-23.

The rejection of Claims 12-23 under 35 U.S.C. 112, second paragraph, for idefiniteness, is withdrawn in view of the cancellation of Claims 12-23.

The rejection of Claims 1-23 under 35 U.S.C. 103(a) is withdrawn in view of Applicant's arguments at the bottom of page 15 of the response and further in view of the cancellation of Claims 12-23. The combination of Tripathy and Dhawan does not provide a reasonable expectation for successfully achieving sustained expression of a self protein for greater than 30 days upon *in vivo* delivery of a viral vector encoding a self protein to muscle cells of an immunocompetent animal. Given the unpredictability in the art of gene transfer and expression, one of skill in the art would not be able to predict *a priori* that any given method or vector would provide for expression with an increase in the circulating level of a self protein for more than 30 days, 60 days, 90 days, or 120 days, as recited in the present claims.

Terminal Disclaimer

The terminal disclaimer filed on May 8, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,613,319 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 24-36 stand rejected and Claim 37 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

(i) a process for increasing the circulating levels of a self protein in the blood stream of an immunocompetent animal, wherein the method comprises delivering an adenoviral vector *in vivo* to muscle cells of said animal by intramuscular injection in an amount sufficient to obtain expression of and increase the circulating level of said self protein in the bloodstream of said animal for a period greater than about 30 days, wherein said self protein is erythropoietin or a growth hormone and undergoes secretion, diffusion or transport to the circulation upon expression *in vivo*; and

(ii) a process for increasing the circulating levels of a self protein in the blood stream of an immunocompetent animal, wherein the method comprises transforming muscle cells of said animal *ex vivo* with an adenoviral vector encoding a self protein to thereby produce transformed muscle cells, wherein said self protein is erythropoietin or a growth hormone and undergoes secretion, diffusion or transport to the circulation upon expression *in vivo*; and delivering said transformed muscle cells by intramuscular injection to said animal in an amount sufficient to obtain expression of and increase the

circulating level of said self protein in the bloodstream of said animal for a period greater than about 30 days,

does not reasonably provide enablement for the full scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are directed to a method for increasing the circulating levels of a self protein in the blood stream of an immunocompetent animal, wherein the method comprises delivering a viral vector *in vivo* to muscle cells of said animal by intramuscular injection in an amount sufficient to obtain expression of and increase the circulating level of said self protein in the bloodstream of said animal for a period greater than about 30 days, wherein said self protein is a polypeptide hormone and undergoes secretion, diffusion or transport to the circulation upon expression *in vivo*.

The specification fails to provide an enabling disclosure for the claimed methods over the full scope because the specification teaches that the only use for the methods are for gene therapy (p. 1, lines 20-22). No other use for the claimed methods are contemplated in the specification. However, the specification does not adequately teach how to use the methods in gene therapy applications. The specification fails to teach any method for transferring any gene into a target cell and expressing that gene at a therapeutic level in a diseased animal. Thus, the specification does not adequately teach how to use the claimed methods.

The claims encompass methods of gene therapy. However, gene therapy is not routinely successful. Therefore, the disclosure must teach how to use the claimed methods with specific guidance. However, the specification does not provide any guidance as to the use of the claimed DNA methods to treat a diseased animal. The specification does not teach the level of gene expression required, the number of transduced cells needed, when or for how long the gene should be expressed, or the frequency of administration of the gene therapy vector required, for treatment of any pathological condition. At the

time the application was filed, the art of administering any type of genetic expression vector to an individual so as to provide a tangible therapeutic benefit was poorly developed and unpredictable. The NIH ad hoc committee to assess the current status and promise of gene therapy reported in December 1995 that "clinical efficacy has not been definitively demonstrated at this time in any gene therapy protocol, despite anecdotal claims...," and that "significant problems remain in all basic aspects of gene therapy" (Orkin and Motulsky, p. 1). In a review article published in Scientific American in June 1997, Theodore Friedmann discusses the technical barriers which have so far prevented successful gene therapy, and states "So far, however, no approach has definitively improved the health of a single one of the more than 2,000 patients who have enrolled in gene therapy trials worldwide" (p. 96). In a review article published in Nature in September 1997, Inder Verma states "Although more than 200 clinical trials are currently underway worldwide, with hundreds of patients enrolled, there is still no single outcome that we can point to as a success story" (p. 239). The instant specification does not adequately teach one skilled in the art how to use the claimed methods for *in vivo* or *ex vivo* gene therapy. Thus, absent any showing that the claimed methods can be used in gene therapy applications to produce the intended therapeutic effect, the claims directed to methods for gene therapy are not enabled by the disclosure.

The gene therapy art as a whole clearly demonstrates that even in the year 2001, despite intensive effort in every aspect of gene therapy, success in the field was quite limited. Furthermore, Rubanyi et al. (2001) was published after the effective filing date of this application and reflects essentially the same opinion of those stated in the other references cited regarding the technical barriers and very limited clinical efficacy. The quotes that Applicants refer to describing the optimism in the field of gene therapy is not indicative of enablement at present, but rather suggest that continued effort should result in successful protocols at some time in the future. However, future potential is not sufficient to demonstrate the need for only routine experimentation rather than undue experimentation, given that the art as a whole demonstrates that intensive effort has met with limited success.

The specification fails to provide an enabling disclosure for the method of increasing the circulating level of any gene product in the blood stream of a primate. The guidance and examples provided in the specification are limited to producing elevated levels of erythropoietin (EPO) in the blood stream of a healthy Cynomolgus monkey. Since methods of gene therapy are not routine for the reasons discussed above, undue experimentation would have been required to produce the desired effect using any other gene.

The specification provides examples demonstrating that serum erythropoietin levels and hematocrits are elevated in Cynomolgus monkeys following a single intramuscular injection of an erythropoietin-encoding adenovirus vector (Example 8). An assessment of the safety of the administered adenovirus vector is also described (Example 9). However, none of the examples are directed to applications that result in treatment of a pathological condition in a primate. Moreover, the specification does not offer any guidance in this regard.

Given the limited working examples, the limited guidance in the specification, the broad scope of the claims, and the unpredictability of using the claimed methods in gene therapy applications, undue experimentation would have been required for one skilled in the art to practice the claimed invention.

At page 7 of the response, Applicants assert that one of ordinary skill in the art would be able to practice the claimed method "in contexts that do not pertain to gene therapy" without undue experimentation in view of the disclosure. No support is offered for this assertion and the remainder of the response is directed entirely to muscle-based gene therapy. There is no further mention made of practicing the claimed methods "in contexts that do not pertain to gene therapy" nor any mention of what specifically those contexts may be. One of skill in the art is left only with an invitation to experiment to figure out how to use the claimed method "in contexts that do not pertain to gene therapy." It is not to be left up to the skilled artisan to figure out how to make the necessary starting materials and then to figure out how to use them to produce the biological effects as recited in the claims. The courts have held that

the disclosure of an application shall inform those skilled in the art how to use applicant's claimed invention, not how to **find out** how to use it for themselves. *In re Gardner et al.* 166 USPQ 138 (CCPA 1970). This specification only teaches what is intended to be done and how it is intended to work, but does not actually teach how to do that which is intended.

At pages 7-8 of the response, Applicants go on to assert that their specification is fully enabling for the full scope of the claims as written. Applicants point to the specification for teaching proteins present in the circulation of an animal, viral vectors that can be used in the invention, *in vivo* and *ex vivo* transformation of muscle cells, and processes for increasing the circulating levels of a self protein in the bloodstream of an immunocompetent animal by delivery of viral vectors to muscle cells *in vivo*, in Examples 5-10. Applicants further assert that the plasmid vectors taught in Examples 1-4 can be applied by one of ordinary skill in the art in the practice of the claimed methods. As regards the working examples, Applicants assert that the data set forth in the specification demonstrates that the processes claimed result in stable long-term expression of a self protein in an immunocompetent subject. However, the data that Applicants refer to pertain only to expression of erythropoietin, and therefore the specific guidance of the specification is extremely limited. As regards the very broad scope of serum proteins and possible vectors that may be used in the claimed methods, the guidance set forth in the specification is in the form of general guidance, rather than the specific guidance that is needed in an art as unpredictable as gene therapy. The only specific guidance provided is for increasing the circulating level of erythropoietin, which has already been acknowledged as enabled.

At page 8 of the response, Applicants dispute the argument that the specification does not provide guidance as to how the claimed processes can be used in the treatment of disease in an animal. In response, Applicants note that "the results set forth in the specification can be safely and effectively applied to treat patients with Epo-responsive anemias." Applicants seem to be addressing a rejection that has not been made. Applicants are reminded that the Examiner has already acknowledged that the

specification is enabling for increasing the circulating levels of erythropoietin. The rejection is directed to the remaining scope of the claim. As noted in the rejection of record, the guidance and examples provided in the specification are limited to producing elevated levels of erythropoietin (EPO) in the blood stream of a healthy Cynomolgus monkey. Since methods of gene therapy are not routine for the reasons discussed above, undue experimentation would have been required to produce the desired effect using any other gene. Thus, the argument that the guidance of the specification would enable one of skill in the art to treat patients with Epo-responsive anemias does not address the rejection of record.

At pages 8-9 of the response, Applicants contend that they are not required to explicitly recite every disease that can be treated using the processes of the invention. The rejection of record does not pertain to a recitation of the diseases that can be treated using the method of the invention. It is acknowledged that the claims cover the treatment of a vast number of widely divergent diseases that may be treated by increasing the circulating level of a vast number of widely divergent serum proteins. Given the huge number of widely divergent diseases that may be treated by expressing any of a vast number of widely divergent serum proteins in the bloodstream using any of a very large number of possible expression vectors in any species of animal, the specification must enable the treatment of a wide variety of diseases by the claimed methods. Here, it enables only the treatment of Epo-responsive anemias.

At page 9, paragraph 2 of the response, Applicants assert that specific guidance pertaining to the level of gene expression required in the context of erythropoietin is provided in the specification at pages 6-8. Applicants note that this section provides detailed information regarding dosage of viral vector and effect of dose modification on serum erythropoietin level and hematocrit. Applicants are again reminded that the Examiner has already acknowledged that the specification is enabling for increasing the circulating levels of erythropoietin. As noted above, the rejection of record is directed to the remaining scope of the claim and therefore this assertion does not address the rejection of record.

At pages 9-10 of the response, Applicants cite Svensson et al. (April 1996) for stating that there has been tremendous growth in the field of gene therapy, for providing an overview of the state of the art regarding muscle-based gene therapy, and for suggesting diseases that could be targeted using gene-based therapy. It is unclear how this contributes to the enablement of the claimed invention, particularly given that the reference seems to disclose no more than the present specification. Growth in the field of gene therapy does not indicate widespread success in the field, but only indicates that **intensive effort** has been applied to the development of gene therapy protocols with minimal success. It does not in any way suggest that a single successful protocol could be readily modified by one of ordinary skill in the art using nothing more than routine experimentation to treat other disparate diseases with different etiologies and different pathological processes.

At page 10 of the response, Applicants cite Wang and Herzog (2005) as evidence that the claimed methods can be used in gene therapy applications to produce a therapeutic effect. However, given that the priority date of the instant application is August 1996, this reference is post-filing art and evidences that considerable undue experimentation was involved in developing a therapeutic protocol for the treatment of hemophilia. The abstract notes the "recent innovative approaches in vector design and delivery, and strategies to circumvent immunological limitations" and concludes that "these studies provide much encouragement for the possibility of future clinical success, but also point out hurdles that still have to be overcome." This is 9 years after the effective filing date of the present application. The reference also notes that "gene therapy for hemophilia has been extensively pursued over the past decade" (page 349, column 1, paragraph 2). The reference reveals that in earlier studies "only sustained expression of sub-therapeutic or transient expression of therapeutic levels had been reported" (page 349, column 2, paragraph 2). The present claims require sustained expression for 30, 60, 90, 120, and 365 days. Thus, the limited success reported in 2005 was preceded by numerous failures, further experimentation, and intensive effort to come up with the "recent innovative approaches in vector design

and delivery" referred to in the abstract. Furthermore, the reference aptly demonstrates that consideration of factors that were not appreciated at the time of the instant invention were crucial in developing the improved method described therein, further demonstrating the intensive effort applied to the development of the protocol. Citing numerous references from 1999, 2001, and 2004, the authors note that "animals with gene deletions or nonsense mutations have a greater risk of inhibitor formation in muscle gene transfer than those with missense mutations" (page 352, column 2, paragraph 1). All subsequent clinical trials for Factor IX gene therapy for hemophilia were limited to subjects having missense mutations. The reference goes on to describe "[a] number of innovative approaches ... under taken in order to improve efficacy and safety of muscle-directed F.IX gene transfer" (page 352, column 1, paragraph 3). Citing a 2005 report, the reference further emphasizes that "[i]n addition to improvements in vector design, delivery techniques may hold the key for optimal therapy. A substantial increase in efficacy of muscle-directed AAV-F.IX delivery has recently been documented for local vascular delivery" (page 353, column 1, paragraph 2). Thus, the reference evidences considerable intensive effort, innovation, and undue experimentation in developing the gene therapy protocol described. Given that Wang and Herzog (2005) is post-filing art, the skilled artisan would not have had the benefit of the teachings contained therein at the time of the instant invention in 1996.

At page 10 of the response, Applicants cite Kay et al. (2000) and Manno et al. (2003) as evidence that the claimed methods can be used in gene therapy applications to produce a therapeutic effect. Again, both references are post-filing art and there is no evidence that the protocols described therein were the result of routine experimentation. As discussed above, consideration of factors that were not appreciated at the time of the instant invention were crucial in developing the limited methods described therein, further demonstrating the intensive effort applied to the development of the protocol. The references evidence further developments in vector design, further experimentation, and strategies for limiting immune responses by selection of specific patient populations, all of which indicate undue

experimentation rather than routine experimentation. Since the references are post-filing art, the skilled artisan would not have had the benefit of the teachings contained therein at the time of the instant invention in 1996.

At page 11 of the response, Applicants assert that the quotes the Examiner refers to in describing pessimism in the field of gene therapy are "not indicative of enablement in the state of the art pertaining to muscle-based gene therapy" and that the quotes merely suggest that continued effort should continue to improve gene therapy technology. Applicants further assert that the instant specification shows that methods of the present invention have found application in the treatment of disease and that the examples can be applied in providing guidance to one of skill in the art to increase serum levels of a protein to treat disease. Applicants further state that, while some experimentation may be required to practice the claimed invention, no sufficient evidence has been set forth by the Examiner to show that any such experimentation would be undue experimentation. On the contrary, ample reasons supporting unpredictability in the field of gene therapy and the need for undue experimentation to enable the full scope of the claims have been provided. The claims cover the treatment of a vast number of widely divergent diseases that may be treated by increasing the circulating level of a vast number of widely divergent serum proteins. Given the huge number of widely divergent diseases that may be treated by expressing any of a vast number of widely divergent serum proteins in the bloodstream using any of a very large number of possible expression vectors in any species of animal, the specification must enable the treatment of a wide variety of diseases by the claimed methods. The claims cover the treatment of disparate diseases with different etiologies and different pathological processes. Applicant's arguments are not commensurate in scope with the scope of the claims, do not adequately rebut the unpredictability in the field of gene therapy, and do not provide any evidence that the entire scope of the claim can be practiced using nothing more than routine experimentation in an art as unpredictable as gene therapy. As the art of record shows, methods for achieving expression of genes at non-therapeutic levels are relatively

routine, but gene expression is not gene therapy. The development of therapeutic protocols in gene therapy is highly unpredictable and must be done on a case-by-case basis. The considerable research effort in the field of gene therapy has been necessitated by the inherent problem of the myriad of parameters that may be adjusted and combined in a myriad of ways to develop therapeutic protocols and the consideration of numerous disease-specific factors that evolve as the research effort progresses. The skilled artisan would not be able to predict which protocols would be successful, among the many possible protocols that could be attempted. Lacking predictability, considerable experimentation is required. Applicant's focus on optimism in the field of muscle-based gene therapy is missplaced because a potential for the future of gene therapy does not constitute enablement, but rather is suggestive of a technology that is still undeveloped, despite considerable effort in the field. One of skill in the art would conclude that the development of gene therapy protocols is not routine if potential successes lie predominantly in the future, not in the past. The references cited in Applicant's response and by the Examiner provide clear evidence that **intensive effort** has been applied to the development of gene therapy protocols with minimal success. None of the gene therapy methods that Applicants point to were developed using routine experimentation. Furthermore, if it was a simple matter to take the vectors used by others and, with routine experimentation, manipulate them and apply them in techniques for the treatment of other diseases, many successful gene therapy protocols would already exist. However, this is not the case, as evidenced by the references cited in the rejection of record. Further **research** is required to accomplish these goals, not routine experimentation. Thus, the references cited by Applicants do not constitute evidence that only routine experimentation is required for the development of gene therapy protocols within the scope of the claims. On the contrary, the references clearly indicate that, in each instance, **intensive investigation** was required to develop experimental protocols. In an unpredictable art, considerable specific guidance is needed from the specification. In the instant case, given the limited guidance in the specification with regard to the design and implementation of vectors for *in vivo* and *ex*

vivo muscle-based gene therapy, the limited applicable working examples directed to administering an Epo-encoding viral vector, and the broad scope of the claims with regard to the disparate diseases covered, the vast number of vectors that could be used, and the widely divergent serum proteins to be expressed, undue experimentation would have been required for one skilled in the art to practice the claimed methods over the full scope.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER